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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/321,882	05/28/1999	RAVINDRA B. UPASANI	1483.0130002	7179

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01/23/2003

STERNE KESSLER GOLDSTEIN AND FOX PLLC
SUITE 600
1100 NEW YORK AVENUE NW
WASHINGTON, DC 200053934

EXAMINER

BADIO, BARBARA P

ART UNIT

PAPER NUMBER

1616

DATE MAILED: 01/23/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/321,882

Applicant(s)

UPASANI ET AL.

Examiner

Barbara P. Badio, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 25-27, 46, 55, 57-59 and 61-75 is/are pending in the application.
- 4a) Of the above claim(s) 63, 66, 67, 70, 71 and 73-75 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 25-27, 46, 55, 57-59, 61, 62, 64, 65, 68, 69 and 72 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). ____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____ 6) ☐ Other: ____

First Office Action on the Merits of a RCE

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on April 5, 2002 has been entered.

2. The numbering of claims is not in accordance with 37 CFR 1.126 which requires the original numbering of the claims to be preserved throughout the prosecution. When claims are canceled, the remaining claims must not be renumbered. When new claims are presented, they must be numbered consecutively beginning with the number next following the highest numbered claims previously presented (whether entered or not).

Misnumbered claims 68-74 been renumbered 68-75 (note: duplication of claim 69).

Status of the Application

3. Based on the election made in Paper No. 6, claims 25-27, 46, 55, 57-59, 61, 62, 64, 65, 68, 69 and 72 will be examined to the extent they read on the elected species and variants thereof (i.e., compounds wherein R₃ is -C(O)-CH₂-Y-G or -C(O)-CH₂-O-

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D). Claims 63, 66, 67, 70, 71 and 73-75 stand withdrawn from further consideration as being drawn to a nonelected invention.

4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Objections

5. Claims ~~25~~, ~~26~~ and ~~65~~^c are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim.

Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form.

The instant claims recite R₃ is "-C(O)-CH₂-O-E". However, the parent claim 46 does not include said limitation and, thus, the instant claims are of improper dependent form.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims ~~25~~, ~~26~~, ~~46~~, ~~55~~, ~~57~~, ~~59~~, ~~64~~, ~~68~~^c and 69 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that

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the inventor(s), at the time the application was filed, had possession of the claimed invention.

The instant claims recite "G" or "D" can be "a N-oxide of a nitrogen containing heteroaryl group". The present specification lacks description of the instantly claimed subject matter and, thus, does not convey to the skilled artisan that applicant, at the time the application was filed, had possession of the claimed invention.

Claim Rejections - 35 USC § 103

8. The rejection of claims 25-27, 46, 55, 57, 59 and 62 under 35 USC 103(a) over Gee et al. (WO 94/27608) is withdrawn.

u 9. The rejection of claims 25-27, 46, 55, 57-59, 61, 64 and 65 under 35 USC 103(a) over Bolger et al. ('917) is maintained and claims 69 and 72 are rejected under 35 USC 103(a) over Bolger et al. ('917).

Applicant argues the reference does not exemplify any compounds wherein the C-21 position is substituted by either aryloxy or heteroaryloxy. Applicant's argument was considered but not persuasive for the following reason.

A reference is evaluated based on what it teaches the skilled artisan in the art at the time of the invention and not just on what is exemplified. The reference teaches (a) an equivalent between various 21-oxy substituents, (b) that R16 can be C₃-C₁₀ heterocyclic radical (see col. 8, lines 1-16) and (c) heterocyclic radicals such as oxazole, pyridine, pyrrole, pyrimidine and thiazole (see col. 11, lines 8-19). Therefore,

making any of the exemplified compounds wherein the C-21 is substituted by a heteroaryloxy would be prima facie obvious. The motivation to make other species as taught by the reference is based on the desire to make additional compounds useful as taught by Bolger.

For this reason and those given in previous Office Actions, the rejection of claims 25-27, 46, 55, 57-59, 61, 64 and 65 under 35 USC 103(a) over Bolger et al. ('917) is maintained and claims 69 and 72 are rejected under 35 USC 103(a) over Bolger et al. ('917).

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u) 10. Claims 25-27, 46, 55, 57-59, 61, 62 and 68 are rejected under 35 U.S.C. 103(a) as being unpatentable over Phillipps et al. ('260).

Phillipps teaches a generic group of pregnane and pregnane derivatives possessing a 3α -hydroxyl group, a 17α -hydrogen atom, a 20-oxo group and at the 21-position the residue of a sulphur nucleophile or a sulphone or sulfoxide group useful as anaesthetic agents (see the entire article, especially col. 1, lines 38-51; col.2, lines 25-59; col. 3, lines 8-12, 36-40, col. 3, line 67 – col. 4, line 2; col. 5, lines 36-68).

The instant claims differ from the reference by reciting compounds not exemplified by the reference. However, the reference teaches R^3 may be a carbon-attached saturated or unsaturated heterocyclic group, such as pyridyl, morpholinyl (see especially col. 3, lines 36-40). Thus, it would have been obvious to one having ordinary skill in the art at the time of the invention to select any of the species of the genus taught by the reference, including that of the instant claims, because an ordinary artisan

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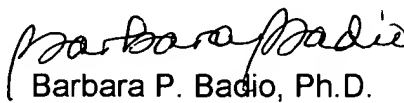
would have the reasonable expectation that any of the species of the genus would have similar properties and, therefore, the same use as the genus as a whole. For example, it would have been obvious to the skilled artisan to modify the compound of example 40 by substituting the 21-(pyrid-2ylthio) group with any 21-heterocyclicthio group with the reasonable expectation that the compound produced would be useful as taught by reference. The motivation to make other species as taught by the reference is based on the desire to make additional compounds having anaesthetic properties.

Telephone Inquiry

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Barbara P. Badio, Ph.D. whose telephone number is 703-308-4595. The examiner can normally be reached on M-F from 7:30am-4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jose Dees can be reached on 703-308-4628. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4556 for regular communications and 703-308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.


Barbara P. Badio, Ph.D.
Primary Examiner
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BB

December 31, 2002